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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,533

01/18/2006

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EXAMINER

CHANDRA, GYAN

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,533	<b>Applicant(s)</b> BEN-SASSON ET AL.	
	<b>Examiner</b> GYAN CHANDRA	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/9/2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 18-20 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 9-14, 18-20 and 22-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7, 8 and 32-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's response filed on 11/12/2007 is acknowledged and fully considered.

#### **Status of Application, Amendments, And/Or Claims**

Claims 1-14, 18-20, and 22-34 are pending.

Claims 1-6, 9-14, 18-20, and 22-31 remain withdrawn from further consideration as being drawn to a non-elected invention.

Claims 7, 8 and 32-34 are under examination.

#### ***Response to Arguments***

##### ***Claim Rejections – withdrawn***

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 7, 8 and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections (i.e., in claim 7 (b) is not complete as the sentence stops at "the variant") is withdrawn in view of applicants' amendments to claim 7 (b). However, upon further consideration of the amendments to claim 7(b), a new ground of rejection is being made under 35USC 112, first paragraph.

#### ***Claim Rejections - 35 USC § 103***

The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Tsui (US Patent No. 6,130,067) is withdrawn in view of applicants' amendments to claim 7 (a) which recites the limitation "a peptide sequence of 4-55 amino acid residues". However, upon further consideration of the amendments made to claim 7, a new ground

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of rejection is made for New Matter. It is noted to applicants that if the new matter is cancelled out, then the previously applied rejection under 35 USC 103(a) would be reinstated.

### **New Ground of Rejection**

#### ***Claim Rejections - 35 USC § 112-New Matter***

Claims 7, 8 and 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claims are not described in the Specification or the Claims as originally filed.

The proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). See MPEP § 2163.06 through § 2163.07 for a more detailed discussion of the written description requirement and its relationship to new matter. The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. In *re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. MPEP 2105.

In the instant application, there is no support in the specification, as originally filed, for the claim limitation “a peptide sequence of 4-55 amino acid residues” selected from the group consisting of (a)-(f). Applicant states that [0042] of the specification on page 9 provides support for the upper limit of “55” residues. However the disclosure

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does not support for a peptide range of any where from 4 aa to 55 aa in length. Claim 7

(a) -(f) does not comprise any fragment of 55 amino acids in length. This is not

persuasive because the specification on page 9, paragraph [0042] states:

“a compound may be composed mainly from amino acid residues, and in that case the amino acid component of the compounds should comprise no more than a total of about 55 amino acids.”

Therefore, the upper limit is "about 55 amino acids" which can be for example, 53, 54, 55, 56, 57 or 58. Additionally, applicant states that page 7, paragraph [0031] a peptide sequence stretch of at least 5 aa combined with a 20% deletion limitation would support the newly cited limitation. This has been fully considered but not persuasive because the disclosure does not recite the limitation " a peptide of 4-55 residues" and by bringing two numbers from different context does not support the instantly claimed invention. Additionally, claim 7(b) says to delete up to 20% of aa of part 7(a) provided that at least 50% of the amino acids in the parent sequence are unaltered (at least 50% of 9 positions 143-151 of rhodopsin is minimum 5 aa residues and 4 aa residues and therefore, the specification does not support for the lower limit of "4" amino acids.

Therefore, claims 7, 8 and 32-34 are rejected under 35 USC 112, first paragraph-**new** matter. Applicant may want to amend the upper limit of "55 amino acid residues" to "about 55 amino acid residues". However this, in itself, will not overcome the rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 7, 8 and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 7, the limitation "4-55 amino acid residues selected from the group consisting of" renders the claim indefinite because the upper limit of amino acid residues (i.e., 55 residues) are not in the groups from which it could be selected. For example in claim 7 (a) recites:

"a peptide sequence which is a continuous stretch of at least 5 amino acids present in the 7TM receptor in positions corresponding to the positions 143-151 of rhodopsin when the 2nd intracellular region of the 7TM receptor is aligned with the 2nd intracellular region of rhodopsin;"

Thus, one skilled in the art would know that residues 143-151 are 9 amino acids but one of the skill in the art would not know regarding other 46 amino acids of the limitation "4-55 amino acid residues" (i.e.,  $55-9 = 46$ ) and from which amino acid sequence they are selected from. The claim requires selecting 4-55 amino acids from claim 7(a) which provides support for selecting up to 9 amino acids and therefore, other 46 amino acids of the limitation "4-55" can not be selected from claim 7 (a). Therefore, the metes and bounds of the claimed invention can not be determined.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gyan Chandra/  
Examiner, Art Unit 1646

/Robert Landsman/  
Primary Examiner, Art Unit 1647